FEB 2 3 2000

K000210

510(K) SUMMARY OF SUBSTANTIAL EQUIVALENCE

Proprietary Name:	Model 5966-37M Lead Adaptor Kit
Common Name:	Pacemaker Lead Adaptor
Device Classification:	Class III
Product Classification and Code:	Adaptor, Lead, Pacemaker, 74DTD
Classification Panel:	Circulatory System Devices Panel
Establishment Registration Number:	2127690
Contact Person:	Michael Johnson Product Regulation Manager Mail Stop: X260 Medtronic, Inc. 4000 Lexington Avenue North Shoreview, MN 55126-2983 Telephone: (612) 514-9835 Facsimile: (612) 514-9954 Pager: (612) 650-4843

Performance Standard

Performance standards do not currently exist for these devices. None established under Section 514.

Device Description

The Model 5866-37M lead adaptor kit The Medtronic Model 5866-37M lead adaptor kit is designed to connect a Medtronic pacing lead with a 5mm unipolar lead connector to a pulse generator featuring a connector block which meets the (IS-1 UNI) standard. The lead adaptor features a MP35N nickel alloy conductor coil, silicone rubber insulation, and a stainless steel connector. The Model 5866-37M is intended for single use only.

The change being made is related to the molding method of the distal portion of the adaptor. Currently, this component is molded out of MDX silicone rubber using a cold transfer molding process. MDX silicone rubber and Dow LSR are the same material, silicone rubber elastomer, as listed in the FDA Biomaterials Compendium. MDX is a one-component peroxide cure chemistry, whereas the LSR material is a two-part silicone rubber that uses a platinum cure chemistry. The finished LSR component meets all product specifications. All biocompatibility and biostability testing have been completed.

Indications for Use

The Medtronic Model 5866-37M lead adaptor kit is designed to connect a Medtronic pacing lead with a 5mm unipolar lead connector to a pulse generator featuring a connector block which meets the IS-1 UNI standard.

Substantially Equivalent Device

The Medtronic Model 5866-37M (subject of this Special 510(k) is believed to be substantially equivalent to the following predicate device currently in interstate commerce:

- Model 5866-37M lead adaptor kit (K904575)

In Medtronic's opinion, the Medtronic Model 5866-37M lead adaptor kit is found to be substantially equivalent to the predicate product with respect to the comparable features, materials of construction and intended use (see table).

The lead adaptor features a MP35N nickel alloy conductor coil, silicone rubber insulation and a stainless steel connector. This kit is intended for single use only.

Labeling, packaging and sterilization of the Model 5866-37M lead adaptor kit is identical to that of the currently marketed device.

	Device in this Submission	**Predicate Devices Referenced in this Submission**
Manufacturer	Medtronic	Medtronic
Model Number	5866-37M	5866-37M
510(k) Number		K904575
Intended Use	To connect a Medtronic pacing lead with a 5mm unipolar lead connector to a pulse generator featuring a connector block which meets the IS-1 UNI standard	To connect a Medtronic pacing lead with a 5mm unipolar lead connector to a pulse generator featuring a connector block which meets the IS-1 UNI standard
Lead Adaptor Type	Unipolar	Unipolar
Application	Connector between lead and pulse generator	Connector between lead and pulse generator
Device Compatibility (minimum)	Pulse generator must meet the IS-1 UNI standard	Pulse generator must meet the IS-1 UNI standard
Conductor Material	MP35N Nickel Alloy	MP35N Nickel Alloy
Outer Insulation Material	Molded Silicone Rubber (LSR)	Molded Silicone Rubber (MDX)
Connector Type	IS-1 Unipolar	IS-1 Unipolar
Included Accessories	Wrenches and setscrew assemblies, tube of medical adhesive	Wrenches and setscrew assemblies, tube of medical adhesive
Sterilization Method	100% Ethylene Oxide (EtO)	100% EtO
Packaging Materials	Spunbonded polyolefin tray and pouch	Spunbonded polyolefin tray and pouch

Summary of Studies

Medtronic, Inc. performed device integrity testing to support that the Medtronic Model 5866-37M lead adaptor kit is equivalent to the predicate device. Device integrity testing included:

- Visual verification
- Dimensional verification
- Electrical verification
- Composite pull test verification
- Connector compatibility

All device integrity test results for the Model 5866-37M lead adaptor kit met specified requirements.

Conclusion (Statement of Equivalence)

Through data and information presented, numerous similarities support a determination of substantial equivalence, and therefore market clearance of the 510(k) notification for the Medtronic Model 5866-37M lead adaptor kit through a **Special 510(k): Device Modification** notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 23 2000

Mr. Mike Johnson
Medtronic Inc.
7000 Central Avenue NE
Minneapolis, MN 55432-3576

Re: K000210
Model 5866-37M Lead Adaptor Kit
Regulatory Class: III (three)
Product Code: 74 DTD
Dated: January 21, 2000
Received: January 24, 2000

Dear Mr. Johnson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): **K000210**

Device Name: Medtronic Model 5866-37M Lead Adaptor Kit

Indications For Use: The 5866-37M lead adaptor kit is designed to connect a Medtronic pacing lead with a 5mm unipolar lead connector to a pulse generator featuring a connector block which meets the IS-1 UNI[1] standard.

[1]IS-1 refers to an International Connector Standard (ISO 5841-3) whereby pulse generators and leads so designated are assured of a basic mechanical fit.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Christy M. Foh — for written.

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number

X

Prescription Use (Per 21 CFR 801.109) OR Over-The-Counter Use (Optional Format 1-2-96)